40 CFR Part 790

[OPTS-42052H; FRL 3687-6]

RIN 2070-AB97

Testing Consent Agreements and Test Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule amends the procedural rule in 40 CFR part 790 governing manufacturers and processors of chemical substances and mixtures (chemicals) who perform testing under section 4 of the Toxic Substances Control Act (TSCA) by eliminating the requirement that certain manufacturers of chemicals subject to section 4 test rules file letters of intent to test or exemption applications unless no other manufacturer of the chemical submits a letter of intent to test. This rule also modifies the requirement to submit study plans at least 45 days prior to initiation of testing by eliminating the requirement unless it is specified in a particular test rule or testing consent order.

DATES: These regulations shall become effective on June 21, 1990. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern (daylight or standard as appropriate) time on May 21, 1990.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: Section 4 of TSCA gives EPA authority to require manufacturers and processors of chemicals to conduct testing relevant to determining the risk to human health and the environment posed by such chemicals. EPA is amending its procedures implementing section 4 rules in response to an argument made by the Chemical Manufacturers Association (CMA) in a meeting to discuss a petition for changes to the Office of Solid Waste (OSW) test rule, published June 15, 1988 (53 FR 22300), about the procedural burden placed on manufacturers who manufacture chemicals in small quantities for research and development (R & D) purposes, and who are subject to section 4 test rules. This rule treats manufacturers of small quantities of chemical substances (small-quantity manufacturers) and manufacturers of chemical substances for purposes of research and development (R & D manufacturers) similar to processors by generally eliminating the requirement to file letters of intent to test or exemption applications. This rule also modifies the requirement to submit study plans to EPA 45 days prior to initiation of testing.

This rule will decrease the public reporting burden, by eliminating, under the circumstances described in this rule, the requirement for small-quantity and R & D manufacturers to submit letters of intent to test or to submit exemption applications.

I. Introduction

One of the issues raised by the CMA petition concerned the burden of section 4 requirements on small quantity R & D manufacturers. CMA argued that these manufacturers are unlikely to perform testing but are obligated, under EPA's current procedures, to monitor their activities and to submit exemption applications from the effective date of the rule to the end of the reimbursement period. The reimbursement period is defined by TSCA as beginning when the final report is submitted to EPA and continuing for at least 5 years. During the reimbursement period, test sponsors may use the exemption applications to seek proportional reimbursement for the costs of testing. In practice, the administrative costs of seeking reimbursement from small-quantity manufacturers would probably exceed the reimbursement. Therefore, CMA argued the requirement imposes an administrative burden without a corresponding practical purpose.

EPA agreed with CMA's argument, but decided that it is not specific to the OSW rule. Accordingly, instead of amending the procedures only for the OSW test rule, EPA has decided to amend the procedures generally to apply to all test rules. Therefore, this rule removes the requirement for certain small-quantity manufacturers and R & D manufacturers to submit letters of intent to test or exemption applications at the early stage of a test rule, while reserving the authority to require compliance later if necessary. Secondly, this rule removes the requirement for a 45-day waiting period between the submission of study plans and the initiation of testing.

II. Final Rule

A. Persons Subject to a Test Rule

Under EPA's procedural rules for section 4 of TSCA, after promulgation of a test rule applicable to manufacturers and processors of a specific chemical (or manufacturers only), manufacturers must either submit a letter of intent to test or an application for exemption from testing (40 CFR 790.45). Submission of these letters or exemption applications is required within 30 days of the effective date of the rule (if the chemical is manufactured by the person as of or within 30 days after the effective date of the rule), or by the date manufacture begins, if the person begins manufacture before the end of the reimbursement period. At present, small-quantity and R & D manufacturers (including importers) are subject to these requirements and typically file exemption applications. EPA grants an exemption upon this application if another manufacturer has notified EPA of its intent to perform the required testing. The exemption applications are used by the test sponsors to seek reimbursement from persons subject to the test rule. Test sponsors legally may seek reimbursement from all persons subject to test rules, including processors, whether or not they have been required to file exemption applications.

Because small-quantity or R & D manufacturing normally represents a small percentage of the overall production volume, test sponsors are not expected to expend the administrative resources to recover the small proportional amounts of the testing costs from these manufacturers. Therefore, filing of exemption applications by these manufacturers serves no practical purpose.

In addition, the present requirement to file exemption applications, as applied to manufacturers who may begin to produce a chemical subject to a test rule solely in small-quantities for the first time after the effective date of the test rule but before the end of the reimbursement period, presents a burden to these manufacturers. Administrative resources are expended

to determine if any chemicals currently subject to testing under section 4 are being manufactured in small-quantities. This may involve keeping track of a substantial number of chemicals.

Under EPA's procedural rules, when both manufacturers and processors are subject to a rule, EPA chooses to treat processors differentiy, therefore reducing the processors' administrative burdens. While manufacturers and processors both are subject to test rules, processors are not required to submit letters of intent to test or exemption applications unless no manufacturer submits a letter of intent to test (40 CFR 790.42) within the time period specified in the procedural rule. However, processors may be subject to a claim for reimbursement by a manufacturer who actually performs the test (40 CFR 791.2). Processors are still subject to export notification requirements as specified in TSCA section 12(b).

This rule amends the procedural rule governing test rules and consent agreements under section 4 of TSCA by treating certain small-quantity and R & D manufacturers similar to processors and will correspondingly alleviate the reporting burden on these persons. Although EPA believes that small-quantity and R & D manufacturers are properly subject to testing and reimbursement requirements under section 4, this rule eliminates the requirement to file letters of intent to test or exemption applications unless no other manufacturer of a chemical substance subject to a section 4 test rule submits a letter of intent to test. As is the case for processors, the small-quantity and R & D manufacturers would still be subject to test rules (and export notification requirements as specified in TSCA section 12(b)), and would not be exempt from reimbursement claims. Thus, this rule would not change the legal rights and obligations of persons subject to section 4 test rules, but would only eliminate some of the paperwork burden associated with compliance.

This change applies to all section 4 test rules, including test rules in effect at the time of promulgation of this rule. Thus, small-quantity manufacturers and R & D manufacturers who are subject to any section 4 test rule at the time of publication of this final rule change would not have to continue to monitor chemicals they manufacture in small-quantities to determine compliance with section 4 rules.

EPA is defining small-quantity manufacturers as those persons who manufacture less than 500 kg (1,100 pounds) per year of a chemical. EPA is defining R & D manufacturers as those who manufacture a chemical in small quantities for research and development (meaning quantities that are not greater than those necessary for purposes of scientific experimentation or chemical analysis or chemical research on, or analysis of, such chemical or another chemical including such research or analysis for development of a product). This definition is consistent with that under 40 CFR 720.3(cc). These manufacturers are subject to the requirement to conduct testing under a test rule during the period from the effective date of the test rule to the end of the reimbursement period, but will only be required to submit letters of intent to test or exemption applications if no other manufacturer of the chemical submits a letter of intent to test. If no manufacturer submits a letter of intent to test, EPA will notify the R & D and the small-quantity manufacturers (and processors as applicable), by Federal Register notice or certified mail, as set forth in 40 CFR 790.48, that they are subject to the requirement to submit letters of intent to test or exemption applications.

EPA reserves the right to differ from the general procedure in this rule by proposing in a specific section 4 test rule to require R & D manufacturers and/or small-quantity manufacturers to submit exemption applications. EPA may do this in cases where it expects that such manufacturers are likely to be sought by test sponsors to pay costs of the testing, or in the case of R & D manufacturers only, where the EPA is proposing testing primarily to assess the risks associated with R & D manufacture of the chemical.

B. Submission of Study Plans

EPA is modifying its requirement in 40 CFR 790.40 that study plans be submitted 45 days prior to initiation of each test, by eliminating the requirement unless specified in a particular test rule or consent order. As stated in the Federal Register of May 17, 1985 (50 FR 20652), under single-phase rulemaking, EPA no longer approves protocols contained within study plans, but may use them to monitor the testing program and schedule audits. EPA is confident that in most cases, submitting study plans less than 45 days prior to initiation of the test would give EPA sufficient opportunity to arrange for laboratory inspections and data audits. Thus, unless necessary for a particular rule or consent agreement, e.g., to examine a novel protocol, EPA will no longer specify how many days prior to initiation of testing a study plan must be submitted.

III. Response to Public Comments

EPA received written comments on the proposed rule from the Dow Chemical Company, Kodak, 3M, Monsanto, Rhone-Poulenc, the Synthetic Organic Chemical Manufacturers Association (SOCMA), and CMA. These comments are discussed in Unit III.A. through F of this preamble.

A. Small Quantities Procedural Exemption

Several commentors supported EPA's proposal to exempt manufacturers of chemicals for non-research and development purposes to 500 kg per year. Some commentors argued that EPA should not establish a small quantity production limitation for R & D chemicals, because R & D status ensures that the chemical will be produced in small quantities. Further, the appropriate "small quantity" varies, depending on the type of chemical involved and its prospective uses.

Some commentors endorsed the 500 kg/year cutoff while others suggested the cutoff be raised to 1000 kg/year. Some indicated that an average or an aggregate production figure over the reimbursement period would be best, while others supported annual production figures. One commentor suggested that for test rules on substances in articles, the figure be based on 1 percent of the total amount of the article, rather than an absolute volume of production. Another commentor suggested that the cutoff be facility-specific to reduce recordkeeping burdens.

EPA agrees that the best way to alleviate the regulatory burden on R & D manufacturers is to exclude all R & D manufacturers from the procedural requirement of submitting letters of intent to test and exemption applications. Therefore, this rule eliminates the recordkeeping burden associated with determining the production volume of an R & D chemical. In the final rule, however, EPA is maintaining a small quantity exemption for non-R & D manufacturers at the 500 kg/year limit. In part, EPA is maintaining the 500 kg/year limit to be consistent with the Preliminary Assessment Information Rule (PAIR). EPA is basing the limit on annual production because, as one of the commentors asserted, production statistics are usually kept on an annual basis, and EPA wishes to use one standard for all companies. EPA has chosen not to accept the suggestion that annual production be facility-specific for non-R & D small quantity producers (R &

D manufacturers no longer have a limit) because to do so could result in an unequal effect between non-R & D manufacturers.

B. General Exemption From Test Rules for R & D

Some commentors suggested that chemicals produced solely for R & D should be excluded altogether from section 4 rules. Thus, rather than placing R & D manufacturers in a "second tier", they would not be legally subject unless specified in a particular test rule. CMA argued that exposure to humans or the environment to R & D chemicals is limited, and R & D chemicals are not commercially viable. Thus, EPA would not be warranted in issuing a section 4 test rule for R & D chemicals. Kodak commented that R & D chemicals should be exempt because they are produced in limited quantities, are not generating economic values from sales, and are essential to innovation.

EPA does not believe that it should grant a total exemption to R & D manufacturers. Section 4 of TSCA gives EPA authority to require testing of chemicals manufactured for R & D. Congress did not exempt R & D manufacturers from being subject to section 4, as in the case of sections 5 or 8 of TSCA. In this rule, EPA has lifted the procedural burden imposed on R & D manufacturers by test rules, recognizing that test sponsors would rarely, if ever, seek reimbursement from R & D manufacturers. By maintaining legal authority over R & D manufacturers, however, EPA has reserved the right of a test sponsor to seek reimbursement from all persons legally subject to a test rule.

Also, EPA disagrees with CMA's contention that no chemicals produced for R & D are commercially viable and should therefore not be subject to section 4 test rules. EPA contends that there may be instances where a manufacturer makes a chemical for a number of entities who will be using the chemical for R & D purposes. Further, EPA anticipates that there may be a future test rule to examine the risks associated with the production of a chemical for R & D purposes. Therefore, EPA reserves the right to propose, in a specific test rule, that the procedural rule exempting R & D manufacturers from submitting letters of intent to test or exemption applications not apply.

C. Non-Isolated Intermediates, Waste By-Products, Impurities

SOCMA commented that EPA should exclude from section 4 all manufacturing and processing of non-isolated intermediates, waste by-products, and impurities. This issue is not within the scope of this rulemaking.

D. Processors

Dow suggested that EPA create a third tier for small quantity processors that would apply only if processors will be subject to the rule. Processor-only test rules have never been issued. Therefore, rather than further complicating the procedural rule, EPA would consider this comment when it is developing any proposed test rule that would require only processors to test.

E. Import

Dow requested that the codified portion of the rule clarify that manufacture means import. This is unnecessary because TSCA section 3 clearly defines "manufacture" as production or import.

F. Study Plan Modification

Several commentors approved of the proposal which is promulgated in the rule. One commentor asked for additional changes to the study plan provisions that are outside the scope of this rulemaking.

G. Miscellaneous Issues

Several commentors requested exemption from import and export provisions of sections 12 and 13 of TSCA. Another commentor suggested that the quantity limit should be raised to 1000 kg and that this should also apply to the Comprehensive Assessment Information Rule (CAIR) and PAIR rules. These issues are outside the scope of this rulemaking.

IV. Rulemaking Record

EPA has established a record for this rulemaking proceeding [docket number OPTS-42052H]. This record contains the basic information considered by EPA in developing this proposal and appropriate **Federal Register** notices.

This record includes the following information:

A. Support Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice of EPA's proposed procedural rule. (54 FR 21237, May 17, 1989).

(b) Notice of final rulemaking on data reimbursement (48 FR 31786, July 11, 1983).

(c) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652, May 17, 1985).

(2) Support documents consisting of the economic impact analysis of the procedural rule.

(3) Communications consisting of:

(a) Written public comments.

(b) Summaries of phone conversations.

(c) Minutes of August 9, 1988, meeting between EPA and CMA.

(4) Reports - published and unpublished factual materials.

B. References

(1) Chemical Manufacturers Association letter and Petition for an Administrative Stay and Modification of the Final Toxic Substances Control Act Section 4 Test Rules on Solid Waste Chemicals (53 FR 22300, June 15, 1988) (July 29, 1988).

(2) Notice of final rulemaking on data reimbursement (48 FR 31786, July 11, 1983).

(3) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652, May 17, 1985).

(4) Minutes of August 9, 1988, meeting between the EPA and the Chemical Manufacturers Association to discuss a petition for changes to the Office of Solid Waste test rule (53 FR 22300, June 15, 1988).

V. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this procedural rule change is not major because it does not meet any of the criteria set forth in section 1(b) of the Order; i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 et seq., Pub. L. 96-354, September 19, 1980), EPA is certifying that this procedural rule will not have a significant impact on a substantial number of small businesses because: (1) They already are not likely to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, and this change would make their participation even more unlikely; (3) this change would reduce the number of small businesses that will experience any costs in securing exemption from testing requirements; and (4) small

businesses are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned OMB control number 2070–0033. This change in the procedural rule for implementation of section 4 of TSCA will reduce the public reporting burden by no longer automatically requiring small-quantity and R & D manufacturers of chemicals to submit applications for exemption from testing.

List of Subjects in 40 CFR Part 790

Chemicals, Environmental protection, Hazardous substances, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: April 30, 1990.

Linda J. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR, chapter I, subchapter R, is amended as follows:

PART 790—[AMENDED]

1. The authority citation for part 790 continues to read as follows:

Authority: 15 U.S.C. 2603.

2. In § 790.42, by adding paragraphs (a)(4) and (a)(5) and (a)(6) to read as follows:

§ 790.42 Persons subject to a test rule.

(a) * * *

(4) While legally subject to the test rule in circumstances described in paragraph (a)(1) of this section, persons who manufacture less than 500 kg (1,100 lb) of the chemical annually during the period from the effective date of the test rule to the end of the reimbursement period, must comply with the requirements of the test rule only if such manufacturers are directed to do so in a subsequent notice as set forth in § 790.48, or if directed to do so in a particular test rule.

(5) While legally subject to the test rule in circumstances described in paragraph (a)(1) of this section, persons who manufacture small quantities of the chemical solely for research and development (meaning quantities that are not greater than those necessary for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such chemical or another chemical, including such research or analysis for development of a product) from the effective date of the test rule to the end of the reimbursement period, must comply with the requirements of the test rule only if such manufacturers are directed to do so in subsequent notice set forth in § 790.48, or if directed to do so in a particular test rule.

(6) If testing is being required to allow evaluation of risks associated primarily with manufacture of a chemical for research and development (R & D) purposes, manufacturers of the chemical for R & D will be subject and must comply with the requirements of the test rule.

* * * * *

3. In § 790.48, by revising paragraphs (a)(2) and (b)(3) to read as follows:

§ 790.48 Procedure if no one submits a letter of intent to conduct testing.

(a) * * *

(2) If no manufacturer subject to the test rule has notified EPA of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule described in § 790.40, EPA will notify all manufacturers, including those described in § 790.42(a)(4) and (a)(5), by certified mail or by publishing a notice of this fact in the **Federal Register** specifying the tests for which no letter of intent has been submitted and will give such manufacturers an opportunity to take corrective action.

* * * * *

(b) * * *

(3) No later than 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section, each person described in § 790.40(a)(4) and (5) and each person processing the subject chemical as of the effective date of the test rule described in § 790.40 or by 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section must, for each test specified in the **Federal Register** notice, either notify EPA by letter of his or her intent to conduct testing or submit to EPA an application for an exemption from testing requirements for the test.

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4. In § 790.50, by revising paragraph (a)(1) to read as follows:

§ 790.50 Submission of study plans.

(a) * * *

(1) Persons who notify EPA of their intent to conduct tests in compliance with the requirements of a single phase test rule as described in § 790.40(b)(1) must submit study plans for those tests prior to the initiation of each of these tests, unless directed by a particular test rule or consent agreement to submit study plans at a specific time.

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